Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

December 10, 2008

Attendees: Chairman Ben Main, Dr. Lucy Culpepper, Dr. Gerard J. Ferris, Ms. Vicki Little Faulk, Dr. Kelli Littlejohn, Dr. Robert Moon, Ms. Latonage Porter, Dr. Joseph Thomas, Dr. Chivers R. Woodruff, Dr. Chad Bissell and Dr. Tina Hisel

Absent: Dr. Michelle Freeman; Dr. Nancy Sawyer

1. OPENING REMARKS

Chairman Main called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:15 a.m.

2. APPROVAL OF MINUTES

Chairman Main asked if there were any corrections to the minutes from the September 10, 2008 P&T Committee Meeting.

There were no objections. Dr. Woodruff made a motion to approve the minutes as presented and Ms. Faulk seconded to approve the minutes. The minutes were unanimously approved.

3. PHARMACY PROGRAM UPDATE

The Agency asked that the speaker be noted in the minutes taken by GHS when motions are made or seconded.

Dr. Littlejohn introduced the Health Information Design (HID) contract group and academic detailers who visit providers throughout the state on behalf of Medicaid and provide education on pharmacy-related issues.

The Agency has changed the release date of provider payrolls effective with the 10/17/08 check write. Further information can be found on the Agency's website.

The Agency has initiated a series of maternity care related Town Hall meetings; the meetings are open to the public. The purpose of the meetings is to solicit input from maternity care providers, P&T advocates and the general public in regards to revamping the Agency's maternity care program, with the goal of increasing the number of healthy babies in the state. More information is available on the Agency's website, http://www.medicaid.alabama.gov/programs/pharmacy_svcs/pharmacy_services.aspx; Dr. Moon is also

available to answer questions. Meetings will be held in Tuscaloosa, Birmingham, Mobile, Montgomery (also in person and via web conference), and Huntsville.

The Agency provided an update on the Cost of Dispensing/SMAC Project for the Pharmacy Services Division, both of which are currently in the validation process. The Agency hopes to bring pharmacy association groups back together in January for an update.

A Positive Antipsychotic Management (PAM) update was provided. It was noted that, as requested by the P&T Committee, the Agency has met with the PAM workgroup, which includes the Department of Mental Health, a group of child psychiatrists and other specialists. Per the Committee's request, a medical chart review was recently completed by the Agency Program Integrity staff on the identified child recipients. The Agency will review the preliminary results and reconvene the workgroup after the holidays.

Per the request of P&T members, the Agency has updated the policy for meeting with members of the manufacturing industry to include language related to manufacturer solicitation of P&T Committee members regarding drugs included in upcoming P&T meetings. P&T members have notified Dr. Littlejohn that manufacturers continue to solicit them in advance of P&T Committee meetings, despite previous public requests for manufacturers to respect the members' Statement of Integrity. Dr. Littlejohn strongly requested that manufacturers abide by the policy and "respect the P&T members' commitment to the State of Alabama by following the procedures available through the P&T policy". Dr. Littlejohn will personally contact those non-compliant manufacturer(s) from today's meeting.

The Agency has updated the Clinical Review Recommendations Overview document for new and long-standing members. The document provides an overview of the options available to the P&T Committee in the review of a drug class for the Preferred Drug Program.

Dr. Littlejohn reminded the Committee as well as the public audience that the Agency accepts cost proposals 365 days per year, and reviews the PDL quarterly for routine updates. The ultimate goal is to have as many cost-effective drugs on the PDL as possible.

Dr. Littlejohn introduced the Pharmacy Clinical Support contractor representatives, Dr. Chad Bissell and Dr. Tina Hisel with Goold Health Systems.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of three pharmaceutical manufacturers. Dr. Littlejohn explained the process and timing system for the manufacturers' oral presentations. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class.

5. PHARMACOTHERAPY CLASS REVIEWS (Please refer to the website for full text reviews.)

The pharmacotherapy reviews began at approximately 9:30 a.m.

Inhaled Antimuscarinics: American Hospital Formulary Service (AHFS) 120808
Manufacturer comments on behalf of these products:

None

Dr. Bissell commented that the ipratropium nebulizer solution is the only inhaled antimuscarinic product that is available generically. Current treatment guidelines that incorporate the inhaled antimuscarinics were discussed. Four guidelines have been updated since the last review, including NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (2007), British Thoracic Society / Scottish Intercollegiate Guidelines Network: British Guideline on the Management of Asthma (2008), NHLBI Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (2007), and NHLBI/WHO Global Initiative for Asthma: Global Strategy for Asthma Management and Prevention (2007).

The inhaled anticholinergics are FDA-approved for the maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. The pharmacokinetics, adverse drug events, drug interactions and dosing and administration sections have not changed since the last review. In March 2008, the FDA released information about an ongoing safety review with tiotropium. A pooled analysis of 29 trials suggested a small excess risk stroke. The results of the UPLIFT trial revealed no increased risk of stroke with tiotropium compared to placebo.

Several new clinical trials measuring efficacy and safety of the inhaled antimuscarinics were added to the clinical packet since the last review in 2006. Dr. Bissell noted that the publication dates of the studies have been included throughout the clinical packet to assist the Committee in recognizing new information. Tashkin et al. (2008) found no significant difference in the rate of decline in FEV_1 when comparing tiotropium to placebo. This was a large, 4-year trial. Dr. Bissell commented that, throughout the class reviews, the American College of Chest Physicians and the American College of Asthma, Allergy and Immunology guidelines state that devices used for the delivery of bronchodilators and steroids are equally effective. Therefore, efficacy should not be the basis for selecting one device over another.

Dr. Bissell concluded that the inhaled antimuscarinics are FDA-approved for the maintenance and treatment of bronchospasm associated with COPD. Tiotropium and ipratropium differ in their pharmacokinetic parameters and pharmacodynamic profiles. Tiotropium has a significantly longer duration of action than ipratropium and has differing effects on cholinergic receptors. Clinical trials have demonstrated that tiotropium significantly reduces COPD exacerbations, improves spirometric indices, and leads to improvements in health-related quality of life and symptom scales compared to ipratropium. According to the GOLD COPD guidelines, none of the existing medications for COPD have been shown to modify the long-term decline in lung function that is the hallmark of this disease. Other than the ipratropium nebulizer solution, there are no generic products available in this class. The two branded products reviewed within the inhaled antimuscarinic class exhibit distinct clinical differences.

Therefore, all short-acting inhaled antimuscarinic brand products within the class reviewed are comparable to each other and to the generics and OTC products (if available) in this class and offer no significant clinical advantage over other alternatives in general use. Tiotropium does offer significant clinical advantages in general use over the other brands, generics and OTC products (if available) in this class and should be available on the Alabama Medicaid Preferred Drug List.

No brand short-acting inhaled antimuscarinics is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands. Tiotropium (Spiriva) is recommended for preferred status.

Dr. Ferris asked that if there is no brand inhaled short-acting antimuscarinic available, then the only short-acting antimuscarinic available would be ipratropium by nebulizer. Dr. Littlejohn replied that Atrovent HFA is currently in preferred status. However, according to this recommendation, there is a possibility that Atrovent HFA would come off the preferred drug list. Chairman Main commented that all long-acting and short-acting agents are presently preferred.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Respiratory β -Adrenergic Agonists Single Entity Agents: AHFS 121208
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that the respiratory β-adrenergic agonists are primarily used for the treatment of asthma, COPD, and exercise-induced bronchospasm. They are divided into short-acting and long-acting agents, and he reviewed which agents fall into the respective categories. The albuterol CFC metered dose inhalers are being discontinued as of December 31, 2008. Since the last review in 2006, there have been two additions to this class of drugs: arformoterol (Brovana®) and formoterol (Perforomist®).

The same four guidelines that were discussed during the inhaled antimuscarinic class review were also updated in this class review. The indications, pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections have not changed since the last review. Dr. Bissell reviewed the boxed warning for the long-acting respiratory β-adrenergic agonists. There have been several new studies added to the effectiveness section of the clinical packet. He informed the P&T Committee members as to where to find those studies in the packet.

Dr. Bissell concluded that the short-acting β-adrenergic agonists are used for the relief of acute symptoms and during exacerbations. The long-acting β-adrenergic agonists are used for the maintenance treatment of asthma and for the prevention of bronchospasm. Overall, the short-acting β-adrenergic agonists have demonstrated similar efficacy and safety in clinical trials. The long-acting β-adrenergic agonists have been shown to be more effective for the maintenance treatment of asthma and prevention of bronchospasm than the routine use of short-acting agents. Guidelines for the management of asthma recommend the use of short-acting β-adrenergic agonists in all stages of the disease. Guidelines for the management of COPD recommend using bronchodilators on a regular basis or as needed to prevent or reduce symptoms. Although both short- and long-acting bronchodilators are effective in COPD, long-acting bronchodilators are more effective than short-acting bronchodilators and should be the treatment of choice in patients who remain symptomatic or have two or more exacerbations per year. No particular β-adrenergic agonist is selected as the preferred agent in the asthma or COPD guidelines. The respiratory β-adrenergic agonists are available in a variety of dosage forms, including inhalation solution, aerosol inhaler, dry powder inhaler, oral solution, and tablets. The CFC products will only be available for a few more weeks.

Therefore, all short-acting respiratory β-adrenergic agonist brand products within the class reviewed are comparable to each other and to the generics and OTC products (if available) in this class and offer no significant clinical advantage over other alternatives in general use. The long-acting respiratory β-adrenergic agonist brand products within the class reviewed offer significant clinical advantages in the maintenance treatment of asthma and prevention of bronchospasm over the short-acting respiratory β-adrenergic agonists, generics and OTC products (if available) in this class and are comparable to each other. However, the long-acting respiratory β-adrenergic agonists are considered add-on therapy and are not considered first-line agents for general use.

Dr. Bissell addressed some recent news reports regarding Serevent®, Advair®, Symbicort® and Foradil®. Some officials within the FDA have recommended that the long-acting respiratory β-agonists, Serevent and Foradil, no longer be used to treat asthma in any patient population, and that Advair and Symbicort no longer be used to treat asthma in pediatric patients due to the increased risk of developing serious respiratory complications. He noted that the FDA could make future recommendations which would affect the decisions of the Committee.

No brand single entity respiratory β-adrenergic agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Dr. Culpepper asked whether the Committee should make an official statement regarding the FDA warning. Dr. Littlejohn replied that Medicaid is coordinating the information received from the FDA (per a previous request from the P&T Committee) and will send information to the Committee when it is released. She recommended against making a recommendation on this topic until the FDA releases their final findings/recommendations. Dr. Moon agreed with Dr. Littlejohn's comments, noting that the concern of two FDA officials was important but that making a broad statement would be premature. Dr. Bissell added that there is not yet a consensus within the FDA regarding this issue and that the view held by a few officials within the FDA should not generally be accepted at this time.

Dr. Woodruff asked about the origin of the news reports. Dr. Bissell replied that the article he referred to was published in the New York Times on December 5, 2008. He noted that there is also information on the FDA website regarding an Advisory Committee meeting being held on December 10 – 11 to review these findings. Dr. Woodruff asked for clarification on the author of the New York Times article and Dr. Bissell confirmed that the author was not from the FDA but rather a reporter for the newspaper. Dr. Littlejohn had a copy of the article for the Committee to review.

Dr. Ferris asked if there were opinions regarding the increased risk with the use of the long-acting β-agonist inhalers in a way other than recommended, specifically as rescue inhalers. Dr. Bissell agreed that long-acting inhalers should not be used as first-line agents or as rescue agents. Dr. Ferris stated that his understanding was that there was nothing inherently more dangerous about using a long-acting inhaler simply because it is long-acting. Dr. Hisel responded that after looking at the FDA briefing document, which reviewed over 100 clinical trials, the data demonstrated a small number of deaths in a pool of over 60,000 patients.

Ms. Faulk asked for clarification on the use of a long-acting β-agonist inhaler with corticosteroids. Dr. Bissell confirmed that the literature suggests that the risk of adverse events was decreased when the two agents were used together.

There was no further discussion on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Respiratory β -Adrenergic Agonists Combination Products: AHFS 121208
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that the combination respiratory β-adrenergic agonists are FDA-approved for the treatment of COPD. The products included in this review include the combination of albuterol and ipratropium. Since the last time this class was reviewed, the product DuoNeb® has become available in a generic formulation.

The only guideline that has been updated since the last review is the NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (2007). The FDA-approved indications, pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections have not changed since the last review.

There has only been one new study published since this class was last reviewed. A study conducted by Tashkin et al. (2007) evaluated albuterol + ipratropium nebulizer four times daily vs. albuterol + ipratropium inhaler four times daily vs. concomitant treatment with a nebulizer (morning and night) and an inhaler (afternoon and evening). Total quality of life score was improved in the concomitant treatment group only. Improvements in the symptoms sub-scores were seen in the nebulizer-only and concomitant treatment groups.

Dr. Bissell concluded that the treatment strategy is based on the severity of COPD. It is recommended that patients in the early stages of the disease are initially treated with a short-acting bronchodilator as needed. However, as the disease progresses, combination therapy is recommended. Two clinical trials reported that the fixed-dose combination of albuterol and ipratropium (administered via a metered dose inhaler) was more effective than monotherapy with either component alone. There are no studies to date that have compared the fixed-dose combination product to the coadministration of albuterol and ipratropium separately. Albuterol, ipratropium and the fixed-dose combination are available in a generic formulation for nebulization. There is only one branded metered dose inhaler in this class.

Therefore, all combination respiratory β-adrenergic agonist brand products within the class reviewed are comparable to each other and to the generics and OTC products (if available) in this class and offer no significant clinical advantage over other alternatives in general use.

No brand combination respiratory β-adrenergic agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Leukotriene Modifiers: AHFS 481024
Manufacturer comments on behalf of these products:
Singulair® (montelukast)- Merck

Dr. Bissell commented that the leukotriene modifiers are a class of medications used for the treatment of asthma. One of the leukotriene modifiers, montelukast, has an additional FDA-approved indication for the treatment of symptoms of seasonal and perennial allergic rhinitis. The leukotriene modifiers can be divided into two pharmacologic categories of compounds: leukotriene-receptor antagonists and 5-lipoxygenase inhibitors. Zyflo® has been voluntarily discontinued by the manufacturer and has been replaced by a controlled-release product, Zyflo CR®. Zyflo® will remain available through pharmacies and wholesalers until current supplies are depleted.

Dr. Bissell noted that the same four guidelines that were discussed during the inhaled antimuscarinic class review were also updated in this class review. The NHLBI Expert Panel Report 3 Guidelines for the Diagnosis and Management of Asthma (2007) list the leukotriene receptor antagonists as an alternative, not preferred, treatment option for asthma. Montelukast has an additional FDA-approved indication for treatment of exercise-induced bronchoconstriction in patients 15 years and older, which is new since the last review. The pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections have not changed since the last review. Zileuton continues to be associated with elevations in liver transaminases, specifically ALT. The manufacturer recommends monitoring serum transaminases at baseline, monthly for the first three months, every two to three months for the remainder of the first year, then periodically thereafter.

There have been four new studies added to the clinical packet. A study conducted by Sorkness et al. (2007) compared three treatments: fluticasone, fluticasone/salmeterol and montelukast. It was a 48–week study which evaluated the percent of asthma control days. Asthma control days averaged 64.2% for fluticasone, 59.6% for the fluticasone/salmeterol combination, and 52.5% for montelukast. This supports the guideline recommendations that montelukast is a good alternative treatment for asthma. A second study conducted by Phillip et al (2007) compared montelukast, salmeterol and placebo for the treatment of exercise-induced bronchospasm. After 2 and 8 hours, both salmeterol and montelukast were effective. However, after 24 hours, only the montelukast was still effective.

Dr. Bissell concluded that current guidelines for the management of asthma recognize that leukotriene modifiers are not as effective as inhaled corticosteroids. Their role is limited to add-on therapy when patients need additional control of their asthma. The guidelines do not give preference to one leukotriene modifier over another. Compared to placebo, leukotriene modifiers demonstrated efficacy in most aspects of asthma control, including pulmonary function, asthma symptoms, β-agonist use, asthma exacerbations, and nighttime symptom control. When compared to other long-term control medications, such as inhaled corticosteroids and long-acting β-agonists, the leukotriene modifiers have not consistently demonstrated equivalence or significant advantages in clinical outcomes. There are no head-to-head trials directly comparing the efficacy and safety of the leukotriene modifiers to each other.

Therefore, all branded products within the class reviewed are comparable to each other and to the generics and OTC products in the class (if available) and offer no significant clinical advantage over other alternatives in general use.

No brand leukotriene modifier is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Dr. Culpepper stated that Singulair is useful in pediatric care when treating allergic rhinitis and asthma. She would like to see it remain on the preferred list. Chairman Main said that he believed Singulair was presently on the PDL. Dr. Littlejohn replied that Singulair is currently under contract and will continue until the contract end date, and will have an opportunity to extend the contract at that time.

Dr. Ferris asked about the need for periodic PA reapplication for respiratory problems, including the documentation required. Dr. Littlejohn explained that prior approval needs to be applied for on a yearly basis. If the child is under the age of five, the Electronic Prior Authorization (EPA) system will automatically assign an approval if the recipient has an asthma diagnosis. Dr. Ferris asked if functional testing was necessary. Dr. Littlejohn further reviewed the respiratory PA criteria listed in the review packet.

Chairman Main asked Dr. Culpepper for clarification on her comment regarding the Singulair PDL status. Dr. Culpepper responded that she was making a comment, not a motion.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Inhaled Mast-cell Stabilizers: AHFS 481032
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that the inhaled mast-cell stabilizers are FDA-approved for the long-term treatment of asthma. Both agents within this class have been shown to reduce asthma symptoms, improve morning peak flow, and reduce the need for short-acting bronchodilators. Even though the improvement seen with inhaled mast-cell stabilizers is less predictable in comparison with inhaled corticosteroids, their safety profile may give them a unique role in asthma management. Tilade® has been voluntarily discontinued by the manufacturer due to multiple factors including the manufacturer's inability to find a qualified manufacturer for a chlorofluorocarbon propellant inhaler. Tilade® will remain available through pharmacies and wholesalers until current supplies are depleted.

Three guidelines have been updated since this class was last reviewed. In general, the mast-cell stabilizers are considered alternative agents for the management of asthma, but not preferred. Cromolyn is indicated for the maintenance treatment of mild-persistent asthma as prophylactic therapy in patients 2 years of age and older. The pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. One new study conducted by Terpeinen et al. (2008) has been added to the packet.

Dr. Bissell concluded that cromolyn inhalation solution is the only generic formulation available in this class. Tilade® has been discontinued by the manufacturer, leaving Intal® as the only brand mast-cell stabilizer

available in an aerosol inhaler. The clinical studies within this review demonstrated comparable safety and efficacy of cromolyn and nedocromil in bronchial asthma control and bronchospasm prevention. In studies comparing cromolyn and nedocromil, there was no significant difference in the clinical markers of asthma severity or control, such as FEV_1, the number of rescue medications used, overall symptom control, and frequency of asthma exacerbations. While cromolyn and nedocromil appear equally effective in treating patients with mild to moderate persistent asthma, inhaled mast-cell stabilizers are generally less effective than other asthma maintenance therapies. National and international guidelines do not currently consider inhaled mast-cell stabilizers for the long-term management of asthma. Clinical studies within this review indicated that inhaled corticosteroids are more effective treatment options for children and adults with mild-moderate persistent asthma. Additionally, inhaled mast-cell stabilizers are less effective in achieving asthma control compared to leukotriene receptor antagonists, as well as long-acting β-adrenergic agonists. One study reported comparable efficacy between nedocromil and sustained-release theophylline. Another study found that while both nedocromil and albuterol provided significantly greater protection against cold dry air challenge compared to placebo, albuterol therapy was more effective than nedocromil.

Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class (if available) and offer no significant clinical advantage over other alternatives in general use.

No brand inhaled mast-cell stabilizers is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Dr. Woodruff asked if the withdrawal of Tilade is permanent. Dr. Bissell replied that he has not received a definitive indication from the manufacturer regarding this issue.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Orally Inhaled Corticosteroids Single Entity Agents: AHFS 680400
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that due to their anti-inflammatory properties, are indicated for use in respiratory disease, primarily asthma. Currently available agents differ in their potency, bioavailability, and dosing schedules. Although agents within the class exhibit different potencies, there is no evidence to support the hypothesis that higher potencies translate to improved efficacy. There are numerous orally inhaled corticosteroid formulations available. These agents are structurally related to endogenously produced corticosteroids but differ in their mineralocorticoid and glucocorticoid activity.

Dr. Bissell noted several changes that have been made since the last review in 2006; the Pulmicort Flexhaler® replaced the Pulmicort Turbuhaler®, the Pulmicort Respules® are available in additional strengths, fluticasone is now available as the product Flovent Diskus®, and mometasone has been reformulated as Asmanex Twisthaler®.

The same four guidelines that were discussed during the inhaled antimuscarinic class review were also updated in this class review. The orally inhaled corticosteroids are considered the most effective treatment for mild, moderate, or severe persistent asthma. The pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections have not changed since the last review. There have been four new studies added to the clinical packet.

Dr. Bissell concluded that the orally inhaled corticosteroids have evolved into the cornerstone of drug therapy for long-term asthma control. The clinical literature reports comparable rates of asthma control among the available products. Available data also supports the potential role of orally inhaled corticosteroids to reduce the need for systemic corticosteroid therapy. All currently published asthma guidelines stress the role of ICS as long-term controller medications. The NHLBI / NAEPP Guidelines state that orally inhaled corticosteroids are the preferred treatment for initiating therapy in children and adults of all ages with persistent asthma. The current guidelines do not give preference to one orally inhaled corticosteroid over another. The current literature does not conclusively report that one orally inhaled corticosteroid is safer or and more efficacious than another.

The role of orally inhaled corticosteroids in the management of COPD remains a debated topic. Although orally inhaled corticosteroids are frequently prescribed in patients throughout multiple stages of the disease, most guidelines stress the use of these agents only in those with severe disease. Current data suggests that orally inhaled corticosteroids do not halt the continuous decline of FEV_1 that accompanies a diagnosis of COPD. Evidence does suggest that orally inhaled corticosteroids may decrease the number of exacerbations in patients with stage III or stage IV COPD and should therefore be reserved for those patients.

Given the role of the orally inhaled corticosteroids in the management of asthma, and the fact that there are no generics available, the single entity brand orally inhaled corticosteroids reviewed in this class offers significant clinical advantage in general use over the generics and OTC products (if available), but are comparable to all other brands in the same class.

Alabama Medicaid should work with manufacturers of brands in the class on cost proposals so that at least one brand single entity orally inhaled corticosteroid is selected as a preferred agent.

Dr. Ferris asked about the safety of the different medications relative to their potency. Dr. Bissell responded that none of the studies in the clinical packet include findings regarding safety based on the medication's potency. He also noted that he does not recall reading any peer reviewed studies on the subject. Dr. Ferris asked if there were studies detailing the use of spacers and whether or not their use improved efficacy. Dr. Bissell responded that he could not recall the specifics of any such studies and that such studies were not included as part of this packet since the literature search was focused on drugs and not devices . Dr. Ferris asked if spacers were covered by Medicaid. Dr. Littlejohn responds by saying that spacers are a covered product, and patients may obtain one with a valid prescription through the pharmacy.

Chairman Main clarified that the recommendation was that at least one brand be preferred. There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Orally Inhaled Corticosteroids Combination Products: AHFS 680400
Manufacturer comments on behalf of these products:
Symbicort® (budesonide and formoterol) Astra-Zeneca

Dr. Bissell commented that the combination orally inhaled corticosteroids are FDA-approved for the treatment of asthma and COPD associated with chronic bronchitis. The products contain formoterol in combination with budesonide, and salmeterol in combination with fluticasone. The long-acting β-agonists are useful for long-term control of persistent asthma and COPD and have been proven to help control nocturnal symptoms. Inhaled corticosteroids are the most effective inhaled anti-inflammatory agents and current treatment guidelines recommend the use of inhaled corticosteroids for long term control in patients with persistent asthma. The budesonide and formoterol formulation is a new addition to the orally inhaled corticosteroid combination products since the last review.

The same four guidelines that were discussed during the inhaled antimuscarinic class review were also updated in this class review. The pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections have not changed since the last review, with the exception of the addition of information on budesonide and formoterol.

Several new studies were added to the effectiveness section of the clinical packet. These include studies conducted by Rabe et al. (2006), Aaron et al (2007), Peters et al ((2007), Sorkness et al (2007), Calvery et al (2007). The study conducted by Pohunek et al. (2006) found no significant difference between budesonide/formoterol and budesonide + formoterol in separate inhalers for morning PEFR, evening PEFR and FEV. Lindberg et al. (2007) compared 4 different treatment groups, including budesonide/formoterol, salmeterol/fluticasone, salbutamol, and placebo. Budesonide/formoterol improved FEV_1 at 5 min to a greater extent than either salmeterol/fluticasone or placebo and to a similar extent as salbutamol,

Dr. Bissell concluded that the current national and international guidelines support the use of both of these agents in combination, but do not indicate a preference for the combination products. The British Thoracic Society guidelines specify that "there is no difference in efficacy in giving inhaled corticosteroids and long-acting β_2 agonists in combination or in separate inhalers". Guidelines do support the coadministration of an inhaled corticosteroid and a long-acting β-adrenergic agonist as first-line treatment for moderate and severe persistent asthma. Numerous studies have demonstrated the efficacy of using the combination of salmeterol, a long-acting β-agonist, and fluticasone, a corticosteroid, in treating asthma. Studies have likewise indicated the efficacy of combinations of formoterol, a long-acting β-agonist, plus budesonide, a corticosteroid in the treatment of asthma. A study by Lindberg et al. comparing combinations of budesonide/formoterol to combinations of fluticasone/salmeterol in a group of 90 patients over a 4-dose, 17 day period found significantly greater improvements in FEV_1 in the formoterol-budesonide group over a 180-minute evaluation period. However, no other significant differences in other observed values and no larger group studies were found. Although the orally inhaled combination corticosteroids have shown to be efficacious compared to monotherapy, guidelines state that patients should be initiated on inhaled corticosteroid monotherapy if they are classified as having mild to moderate disease.

Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products (if available) in the class and offer no significant clinical advantage over other alternatives in general use.

No brand orally inhaled combination corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

The Committee adjourned at 10:45 AM for a break.

The Committee reconvened at 11:00 AM.

Respiratory Smooth Muscle Relaxants Single Entity Agents: AHFS 861600
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that the respiratory smooth muscle relaxants, all of which are xanthine derivatives, are approved by the FDA for the treatment of reversible airway obstruction in asthma, chronic bronchitis, and emphysema. These agents restore pulmonary function through direct respiratory smooth muscle relaxation and suppression of airway responsiveness to stimuli through their immunomodulatory and anti-inflammatory effects. Xanthines are often carefully titrated according to weight-based dosing due to their narrow therapeutic index. The goal serum levels are institution-specific. Due to risk-benefit ratio concerns and the increased availability of safer alternatives, xanthine derivatives maintain a role as second- or third-line agents in all its approved indications.

The same four guidelines that were discussed during the inhaled antimuscarinic class review were also updated in this class review. The sustained-release theophylline is considered an alternative, but preferred, treatment of mild to moderate persistent asthma. The pharmacokinetics, adverse drug events, drug interactions, dosing and administration, and effectiveness sections have not changed since the last review.

Dr. Bissell concluded that theophylline is the representative xanthine in the class. Theophylline is the most often studied and mentioned xanthine in consensus guidelines and is available in the greatest number of dosage forms. Xanthines share similar narrow therapeutic indexes, drug interactions, adverse drug events, precautions, and contraindications. According to the clinical studies within this review, oral sustained-release theophylline demonstrates slightly lower to equal efficacy in improving pulmonary function- and quality-of-life-related parameters compared to inhaled corticosteroids, inhaled long-acting β-adrenergic agonist, nedocromil, cromolyn, or ipratropium when administered in equipotent doses in asthma management. According to national and international consensus guidelines, oral sustained-release theophylline is viewed as an alternative adjunctive long-acting bronchodilator used for long-term control and prophylaxis of asthma symptoms. Due to its modest clinical efficacy, adverse effects, and narrow therapeutic index, theophylline is generally second-line to inhaled long-acting β_2-agonists in bronchodilation. Theophylline also has a place in therapy as a first-line agent in patients with concerns or contraindications to inhaled corticosteroid use.

For COPD, theophylline serves as a bronchodilator that is used as an adjunctive agent in patients with stable COPD who do not respond appropriately to β_2-agonist, inhaled corticosteroids, or anticholinergics. In this situation, slow-release theophylline is seen as a comparable alternative to β_2-agonists, anticholinergics, and oral glucocorticoids. Direct comparison trials within this class are limited and there is insufficient evidence that demonstrates that one respiratory smooth muscle relaxant is safer or more effective than another.

Therefore, all brand products within the class reviewed are comparable to each other and to the generics and over-the-counter products in this class (if available) and offer no significant clinical advantage over other alternatives in general use.

No brand single entity respiratory smooth muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Respiratory Smooth Muscle Relaxants Combination Products: AHFS 861600
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that the combination respiratory smooth muscle relaxants consists of three ingredient combinations which are FDA-approved for adjunctive therapy in the acute management of bronchial asthma or reversible bronchospasm associated with chronic bronchitis and emphysema. Each of these combination products contains a methylxanthine (theophylline or dyphylline) and a guaifenesin component. One product also includes pseudoephedrine.

The same four guidelines that were discussed during the inhaled antimuscarinic class review were also updated in this class review. The pharmacokinetics, adverse drug events, drug interactions, dosing and administration, and effectiveness sections have not changed since the last review. There are limited published clinical head-to-head trials evaluating the safety and efficacy of the combination respiratory smooth muscle relaxants. National and international consensus guidelines do not address the place in therapy of combination respiratory smooth muscle relaxants.

Dr. Bissell concluded that published data concerning the combination agents is limited to bioavailability studies. The usefulness of the study data was questionable due to study limitations and the use of single drug entities in most treatment groups. The combination respiratory smooth muscle relaxants share many similar drug-to-drug interactions and common adverse events which are mostly due to the xanthine component. National and international guidelines do not address the safety or efficacy of combination smooth muscle relaxants in asthma or COPD. However, the ACCP guidelines provide a brief commentary on the use of guaifenesin and theophylline as individual agents in the management of cough related to asthma and chronic bronchitis. According to these guidelines, oral theophylline may have a role in improving chronic bronchitis-related cough in patients with stable COPD. Direct comparison trials within this class are limited and there is insufficient evidence that demonstrates that one combination respiratory smooth muscle relaxant is safer or more effective

than another. In addition, there is no data to support that these products offer significant clinical advantages over administration of their individual components.

Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class (if available) and offer no significant clinical advantage over other alternatives in general use.

No brand combination respiratory smooth muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Intranasal Corticosteroids: AHFS 520808
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that intranasal corticosteroids are primarily used to treat allergic rhinitis, which is inflammation of the nasal passages in response to an allergen. Two currently available intranasal corticosteroids, beclomethasone and mometasone, are also FDA-approved for the treatment of nasal polyps. Flunisolide and fluticasone are available in a generic nasal spray formulation. Two new products have been added to this class review, including ciclesonide (Omnaris®) and fluticasone furoate (Veramyst®).

There have been three changes to the clinical guidelines since this class was last reviewed. These include The American Academy of Allergy, Asthma, and Immunology / American College of Allergy, Asthma and Immunology / Joint Council on Allergy, Asthma and Immunology: The diagnosis and management of rhinitis: An updated practice parameter (2008), the Institute for Clinical Systems Improvement (ICSI): Rhinitis (2008), and the World Health Organization, GA^{2}LEN and AllerGen: Allergic Rhinitis and its Impact on Asthma (2008). Intranasal corticosteroids are the first-line therapy in patients with moderate to severe disease and are also effective against ocular symptoms.

Beclomethasone is an approved treatment for nasal polyps and both beclomethasone and fluticasone are approved for the treatment nonallergic rhinitis. The pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections have not changed since the last review, with the exception of the addition of the new products that have been added to this class review. Two new clinical trials were published since the last review, but that both compared the newer agents to placebo and the outcome was as expected.

Dr. Bissell concluded that there is no substantial evidence that shows one intranasal corticosteroid to be more efficacious or safer than the other available intranasal corticosteroids. The minor differences in sensory perceptions have not been shown to translate to improved outcomes. Fluticasone propionate and flunisolide are available generically.

All brand products within the class reviewed are comparable to each other and to the generics and over-the-counter products in that class (if available) and offer no significant clinical advantage over other alternatives in general use.

No brand intranasal corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Eye, Ear, Nose, and Throat Preparations- Antiallergic Agents: AHFS 520200
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that the antiallergic agents provide symptomatic relief and prevent complications in allergic and immunologic conjunctivitis by preventing histamine release. Some agents are also available in an intranasal formulation to provide symptomatic relief of allergic rhinitis. The therapeutic agents used in allergic and immunologic conjunctivitis include topical corticosteroids, systemic antihistamines, and ketorolac (a topical nonsteroidal anti-inflammatory agent approved for this indication). When treatment is required to target multiple allergic symptoms, options include systemic antihistamines and nasal formulations. However, if treatment is required for isolated ocular symptoms, topical agents are the treatment of choice. Topical agents can vary in their therapeutic effect due to differences in their pharmacokinetic properties. New additions to the clinical packet include olopatadine ophthalmic solution (Pataday®) and olopatadine nasal solution (Patanase®).

No changes in clinical guidelines for these agents have been made since the last review. He noted the pharmacokinetics, adverse drug events, drug interactions, and dosing and administration sections have not changed since the last review. No new studies had been added to the evidence based review since the last review of this class.

Dr. Bissell concluded that the products in the antiallergic agent therapeutic class are further divided by their specific action as either selective histamine H_1-receptor antagonists, mast-cell stabilizers, or combination relatively selective histamine H_1-receptor antagonists with mast cell stabilizing properties. Pharmacokinetic differences between these categories impact their therapeutic action and the time to onset. All agents with antihistaminic properties will treat the primary, acute symptoms of allergic conjunctivitis. However, mast-cell stabilizers, such as cromolyn sodium, do not have immediate antihistaminic properties and are more effective when used chronically in the prevention of allergic symptoms. There are limited clinical studies comparing brand products to the older generic cromolyn sodium. Some evidence shows that olopatadine 0.1% may be more efficacious than epinastine 0.05%, nedocromil 2%, and azelastine 0.05% for reducing itching. However, comparable efficacy versus other agents in this class is not available.

Therefore, all brand EENT antiallergic agents are comparable to each other and to the generics and OTC products in the class (if available) and offer no significant clinical advantage over other alternatives in general use.

No brand EENT antiallergic agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

Eye, Ear, Nose, and Throat Preparations: Vasoconstrictors AHFS 523200
Manufacturer comments on behalf of these products:
None

Dr. Bissell commented that the vasoconstrictors provide temporary relief of the nasal congestion, ocular congestion, and redness that occur in conditions such as allergic rhinitis, the common cold, sinusitis, hay fever, or other respiratory allergies. While it is recognized that this drug class is largely represented by low-cost, generic products (many of which are available over-the-counter), the Pharmacy and Therapeutics Committee is conducting this analysis to determine the clinical utility of promoting select vasoconstrictor agents (either as single agents or in combination with other generic agents) ahead of the branded ophthalmic antiallergic agents.

There have been no changes to the clinical guidelines, pharmacokinetics, adverse drug events, drug interactions, dosing and administration, and clinical efficacy sections since the last review.

Dr. Bissell concluded that the topical vasoconstrictors are indicated for the temporary relief of the signs and symptoms associated with conjunctivitis and rhinitis. Rebound ocular and nasal congestion is a common adverse effect when these agents are used more often than the recommended daily dose. The scientific evidence regarding the efficacy of the EENT vasoconstrictors is extremely limited. The only comparative information available compares pheniramine plus naphazoline to olopatadine (an antihistamine). However, there are no trials found that compared one vasoconstrictor agent to another. At this time, there is insufficient information to conclude that any single vasoconstrictor is safer or more efficacious than others in the class. Naphazoline and phenylephrine ophthalmic solutions are available in generic formulations.

Therefore, all brand topical vasoconstrictors within the class reviewed are comparable to each other and to the generics and OTC products (if available) in the class and offer no significant clinical advantage over other alternatives in general use.

No brand EENT vasoconstrictor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

6. NEW DRUG REVIEWS

Simcor® (niacin extended-release/simvastatin) AHFS 240608 HMG-CoA Reductase Inhibitors
Manufacturer comments on behalf of these products:
Simcor® (niacin/extended release/simvastatin) Abbott

Dr. Bissell noted that this class of cholesterol lowering agents was last reviewed in May 2008. The HMG-CoA reductase inhibitors are often used as first-line agents to decrease LDL cholesterol. Studies have shown that the use of HMG-CoA reductase inhibitors not only lower LDL-cholesterol, but also decrease cardiovascular morbidity and mortality in certain patient groups, regardless of the baseline LDL level. Although there is not enough clinical data to support achieving a certain HDL goal, studies have suggested that low HDL levels still imply a certain degree of cardiovascular risk, even in the setting of normal LDL values.

Niacin extended-release/simvastatin is a combination product containing both extended-release niacin and the HMG-CoA reductase inhibitor, simvastatin. Both the individual agents have demonstrated safety and efficacy in the treatment of dyslipidemia. To date, there is no evidence of a cardiovascular morbidity or mortality benefit with the niacin extended-release/simvastatin combination product over compared with simvastatin monotherapy and niacin monotherapy.

Niacin extended-release/simvastatin is FDA-approved to reduce total cholesterol, low density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), non-high density lipoprotein cholesterol (non-HDL-C), or triglycerides (TG), or to increase HDL-C in patients with primary hypercholesterolemia. It is also indicated for mixed dyslipidemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate. It is also indicated to reduce triglycerides in patients with hypertriglyceridemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate. Several clinical studies that compare the safety and efficacy with the niacin extended-release/simvastatin product were added to the clinical packet.

Dr. Bissell concluded that the published clinical trials have widely demonstrated that both niacin and simvastatin alone are safe and effective in the treatment of dyslipidemia. Studies also support that the combination of simvastatin and extended-release niacin results in a significant decrease in non-HDL cholesterol and a significant increase HDL cholesterol, when compared to simvastatin alone. The side effect profile of the niacin extended-release/simvastatin combination products is similar to the individual components, though special notice should be given to the possible increase in myopathy and increase in abnormal liver function tests when given in combination, as the use of each individual agent alone may result in these adverse outcomes. Although the combination of niacin extended-release/simvastatin has been shown to be efficacious compared to monotherapy, there are no studies to date that have compared the fixed-dose combination product to the coadministration of extended-release niacin and simvastatin separately.

At this time, there is insufficient data to conclude that the niacin extended-release/simvastatin combination product is safer or more efficacious than other brands, generics, and OTC products within the class reviewed (if available) and offer a significant advantage over other alternatives in general use.

No brand combination niacin extended release/simvastatin product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Dr. Ferris asked about sustained-release niacin and its apparent major benefit over the immediate-release niacin product to decrease flushing. He also asked if the only other difference between the sustained-release products and the immediate-release products is a small amount of dyspepsia. Dr. Bissell replied that when the class was reviewed in May 2008, OTC dietary supplements were discussed. OTC dietary supplements with niacin should not be used in exchange for extended-release niacin (available by prescription) because OTC supplements are not regulated by the FDA and the amount of niacin may vary from product to product and within lots of the same brand. Prescription niacin offers clinical advantages over OTC products and was recommended for preferred status. Currently, Niacor and Niaspan are preferred as a result.

Dr. Littlejohn clarified that questions from the Committee are to be held until after the clinical presentation from Goold, and per policy manufacturers should not be directed toward manufacturers.

There were no further discussions on the agents in this class. Chairman Main asked the P&T Committee Members to mark their ballots.

7. RESULTS OF VOTE ANNOUNCED

Dr. Littlejohn announced the results of voting for each of the therapeutic classes and announced that all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

8. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for 9:00 a.m. on February 11, 2009 at the Alabama State Capitol Auditorium.

9. ADJOURN

There being no further business, Dr. Woodruff moved to adjourn, and Dr. Thomas seconded.

The meeting was adjourned at 11:38 AM.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
December 10, 2008

A. Recommendation: No brand inhaled short-acting antimuscarinic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands. Tiotropium (Spiriva®) is recommended for preferred status.

Amendment: None

Vote: Unanimous to approve as recommended

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

B. Recommendation: No brand single entity respiratory β-adrenergic agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

C. **Recommendation:** No brand combination respiratory β-adrenergic agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moorman ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

D. **Recommendation:** No brand leukotriene modifier is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moorman ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

E. **Recommendation:** No brand inhaled mast-cell stabilizer is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

F. **Recommendation:** Alabama Medicaid should work with manufacturers of brands in the class on cost proposals so that at least one brand single entity orally inhaled corticosteroid is selected as a preferred agent.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

G. **Recommendation:** No brand combination orally inhaled corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore M.D. ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

H. **Recommendation:** No brand single entity respiratory smooth muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore M.D. ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

I. **Recommendation:** No brand combination respiratory smooth muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

J. **Recommendation:** No brand intranasal corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

_____ ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

K. **Recommendation:** No brand EENT antiallergic agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☐ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

L. **Recommendation:** No brand EENT vasoconstrictor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☐ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

M. Recommendation: No brand combination niacin extended-release/simvastatin product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Medical Director

_____ ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner

Respectfully submitted,

Chad M. Bissell

December 10, 2008

Chad Bissell, Pharm. D. Date